LEGISLATIVE SERVICES AGENCY
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FISCAL IMPACT STATEMENT

LS 6278
BILL NUMBER: SB 262

NOTE PREPARED: Jan 28, 2014
BILL AMENDED: Jan 23, 2014

SUBJECT: Biosimilar Drugs.

FIRST AUTHOR: Sen. Hershman
FIRST SPONSOR: Rep. Clere

BILL STATUS: As Passed Senate

FUNDS AFFECTED: X **GENERAL**
DEDICATED
FEDERAL

IMPACT: State

Summary of Legislation: (Amended) This bill allows a pharmacist to substitute an interchangeable biosimilar product for a prescribed biological product if certain conditions are met.

The bill requires a pharmacist to record in a certain manner the name and manufacturer of a biologic product that the pharmacist is dispensing not later than ten days after dispensing the biologic product.

The bill requires the Board of Pharmacy to maintain a link on the Board's website to the current list of all biological products that are determined by the United States Food and Drug Administration to be interchangeable with a specific reference biological product. It allows the Board of Pharmacy to adopt rules.

The bill provides that a written or electronic prescription for a biological product must comply with the existing prescription form requirements.

(The introduced version of this bill was prepared by the Health Finance Commission.)

Effective Date: July 1, 2014.

Explanation of State Expenditures: The bill will affect the dispensing process of interchangeable biosimilar biological products. There currently are no such products on the U.S. market; the FDA is in the process of determining how interchangeability can be established for these products. The Medicaid Program and the Children's Health Insurance Program (CHIP) are exempt from the requirements of the bill.

The Indiana Professional Licensing Agency (IPLA) reports that the Board of Pharmacy Internet requirement

can be accomplished within the level of resources currently available to the agency.

(Revised) *Additional Information - Biosimilar Biological Products:* Current Indiana law provides for the substitution of generic drugs for brand name drugs, but does not provide consideration for the substitution of drugs defined as biological products. The bill defines biological products, biosimilar products, and interchangeable biosimilar products. The bill allows for the substitution of interchangeable biosimilar products by a pharmacist so long as the prescription indicates substitution is allowable, the customer is advised of the substitution, and the prescriber is notified of the substitution within 10 days. As defined by the bill, many biological products are currently sold in the U.S. As defined by the bill, biosimilar products are highly similar to the reference product. Biosimilars will have brand names. The Food and Drug Administration (FDA) is currently working on rules for introducing biosimilars - defining a process different from that for generic drugs to demonstrate the safety and efficacy of biosimilar and interchangeable biological products. Currently, there are no interchangeable biological drugs available on the U.S. market.

Explanation of State Revenues:

Explanation of Local Expenditures:

Explanation of Local Revenues:

State Agencies Affected: IPLA, Board of Pharmacy.

Local Agencies Affected:

Information Sources: IPLA; U.S. Food and Drug Administration, Part 15 Hearing on the Approval Pathway for Biosimilar and Interchangeable Biological Products at: http://www.fda.gov/downloads/Drugs/NewsEvents/UCM289130.pdf

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